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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,542	08/07/2006	Takayuki Hida	2006_1298A	5101

513 7590 10/17/2008

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,542	HIDA ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/21/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *4-13,16-35 and 47-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 14, 15 and 36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/7/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/06;10/13/06;11/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Election filed 7/21/08 to the Restriction Requirement mailed 6/20/08 has been entered into the record.

B. Claims 1-52 are pending. Applicant's election of Group I, claims 1-3, 14, 15 and 36-46 in the reply filed on 7/21/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Specification

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title, for example, is suggested: Methods of affecting feeding and weight in mammals by administration of relaxin-3".

B. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and **legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

C. The specification is objected to since the Brief Description of the Figures does not correspond to the panels in the actual Figures. In other words, the Brief Description of Figure 4 should be amended from "Fig 4.", for example, "Fig. 4A-B." or "Fig 4A and 4B". Figure 10 should be amended accordingly.

D. Though none could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject

matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

E. Though none could be found, trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

F. Though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.

3. Claim Objections

A. Claims 37, 39, 41, 43, 45 and 46 are objected to since they depend from non-elected claims. In addition, the test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim (MPEP 608.01(n) – III).

4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for stimulating feeding, increasing body weight and increasing epididymal fat in male Wistar rats, does not reasonably provide enablement for a method of stimulating feeding, increasing body weight, or increasing any other type of fat weight in any other mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming a method of stimulating feeding and increasing body weight in a mammal other than a male Wistar rat, or for increasing fat weight other than by increasing epididymal fat in male Wistar rats. The specification has only provided guidance and working examples of stimulating feeding and increasing body weight in male Wistar rats as well as increasing only epididymal fat in male Wistar rats(Example 11). No other guidance or working examples of stimulating feeding or increasing body weight in any other mammal other than a male Wistar rat, or for increasing any fat other than epididymal in male Wistar rats have been provided in the specification, nor is it predictable what other types of fat would be increased other than epididymal, nor if mammals other than male Wistar rats would benefit from relaxin-3 as recited in claims 1 and 2. If the Examples in the specification (using male Wistar rats as well as the methods outlined to determine the effects of relaxin-3) were well-known at the time of the instant invention (i.e. art-accepted model), then it is suggested that Applicants provide evidence to that effect.

However, for the reasons discussed above reasons, the Examiner has concluded that undue experimentation would be required to practice the invention as claimed.

B. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for stimulating feeding, increasing body weight and increasing epididymal fat in male Wistar rats, does not reasonably provide enablement for a method of treating any and all diseases which require body weight gain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The breadth of the claims is excessive with regard to treating any disease requiring body weight gain. While the guidance and working examples do support the assertion that relaxin-3 can stimulate feeding, increase body weight and increase epididymal fat in male Wistar rats, there is no guidance that any disease requiring body weight gain can be treated. It is well known in the art that AIDS and various cancers lead to body weight loss, for example. However, it would not be expected that relaxin-3 would be

able to treat AIDS and cancer. Relaxin-3 may very well be able to increase body weight gain in a mammal having a disease involving weight loss, or to treat a symptom or sign of the disease (e.g. "a method of increasing body weight in a patient having a disease and in need of said increase…), but there is some concern regarding claiming that relaxin-3 can treat any disease simply by increasing weight, even when the disease is associated with weight loss. Applicants are invited to point to a specific definition of "treat" in the specification, or in the art known at the time for consideration. Respectfully, however, saying "we can treat his cancer by administering relaxin-3" appears misleading under the circumstances.

Regarding claim 15, if Applicants are able to demonstrate that their animal model is an art-accepted model for identifying compounds for increasing weight and fat among various species, then Applicants would be enabled for anorexia and cachexia.

C. Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for stimulating feeding, increasing body weight and increasing epididymal fat in male Wistar rats, does not reasonably provide enablement for a method of reducing these effects, or decreasing any other type of fat weight in any other mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This rejection is basically identical to paragraph A above and the issues can be resolved in a similar manner. Basically, while Applicants have shown that relaxin-3 is able to increase certain weight-related effects, the specification has not demonstrated that an SALPR antagonist would be able to meet the limitations of claims 36-46.

Even, arguendo, the claims were enabled for specifically taught SALPR inhibitors (which the Examiner is unable to find disclosed in the specification), the fact remains that claims 37, 39, 41, 43, 45 and 46 depend from non-elected claims which, themselves, are drawn to screening methods. However, no compounds have been identified. Therefore, these claims are **"reach-through"** claims, wherein Applicants are claiming methods of treating an individual by using any compound identified by a screening method, when no such compound has been identified.

Regarding claim 7, Applicants provide no guidance or working examples of a functional "**partial polypeptide**" able to act as a relaxin-3 receptor. No critical residues have been identified which must be present in order to retain the function of the full-length protein, nor would it be predictable what residues must be retained.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 37, 39, 41, 43, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims depend from non-elected claims which, themselves, are drawn to screening methods. However, no compounds have been described in these screening methods. Therefore, these claims are "**reach-through**" claims, wherein Applicants are claiming methods of treating an individual by using any compound identified by a screening method, when no such compound has been described in the specification. These can also be considered genus claims since the claims potentially encompass an entire genus of molecules including organic and inorganic small molecules, peptides, polypeptides and polynucleotides

Furthermore, regarding claim 7, Applicants provide no description of a functional "**partial polypeptide**" able to act as a relaxin-3 receptor. No critical residues have been identified which must be present in order to retain the function of the full-length protein, nor would it be predictable what residues must be retained.

6. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 36 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 recites the acronym "SALPR". This term should be defined (spelled out) upon first use in the claims.

7. Art of Interest

A. Both Summerlee et al. (Endocrinology) and Sunn (PNAS) teach that relaxin increases drinking (Abstract of both), which would meet the limitation of claim 2 since animals drinking water would gain weight. However, neither reference specifically teaches relaxin-3 and the Examiner cannot make a prima facie case that relaxin-3 would act as does the relaxin in these references.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647